AUG - 4 1999

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#3

AUG - 4 1999

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PO Box 19088
Washington DC 20036

In Re: Patent Term Extension
Application for
U.S. Patent No. 4,757,057

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,757,057, which claims the human drug product NORMIFLO (ardeparin sodium), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 5 years.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Commissioner will issue a certificate of extension, under seal, for a period of 5 years.

The period of extension has been calculated using the Food and Drug Administration determination of the length of the regulatory review period published in the Federal Register of October 13, 1998 (63 Fed. Reg. 54717). Under 35 U.S.C. § 156(c):

Period of Extension = ½ (Testing Phase) + Approval Phase
= ½ (1,883 - 264) + 1,620
= 2,430 (6.7 years)

Since the regulatory review period began October 22, 1987, before the patent issued (July 12, 1988), only that portion of the regulatory review period occurring after the date the patent issued has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). (From October 22, 1987 to July 12, 1988 is 264 days; this period is subtracted for the number of days occurring in the testing phase according to the FDA determination of the length of the regulatory review period.) No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

The five year limitation of 35 U.S.C. § 156(g)(6)(A) applies in the present situation because the patent was issued after the date of enactment of 35 U.S.C. § 156. Since the period of extension calculated under 35 U.S.C. § 156(c) for the patent cannot exceed five years under 35 U.S.C. § 156(g)(6)(A), the period of extension will be for five years.

The 14 year limitation of 35 U.S.C. § 156(c)(3) does not operate to further reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.:	4,757,057
Granted:	July 12, 1988
Original Expiration Date[1]:	July 12, 2005
Applicant:	Fernando Fussi, et al.
Owner of Record:	Pharmacia & Upjohn Aktiebolag
Title:	Oligo-Heteropolysaccharides Having a Heparin-Like Activity, Method for Their Preparation and Pharmaceutical Compositions Based Thereon
Classification:	514/56
Product Trade Name:	NORMIFLO (ardeparin sodium)
Term Extended:	5 years
Expiration Date:	July 12, 2010

Any correspondence with respect to this matter should be addressed as follows:

By mail: Assistant Commissioner for Patents
Box Patent Ext.
Washington, D.C. 20231

By FAX: (703) 308-6916
Attn: Special Program Law Office

By hand: Crystal Plaza Four, Suite 3C23
2201 South Clark Place
Arlington, VA 22202

[1]Subject to the provisions of 35 U.S.C. § 41(b).

Telephone inquiries related to this determination should be directed to the undersigned at (703) 306-3159.

Karin Tyson
Senior Legal Advisor
Special Program Law Office
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

cc: David T. Read
Acting Director Regulatory Policy Staff, CDER
Food and Drug Administration
1451 Rockville Pike, HFD-7
Rockville, MD 20852

RE: NORMIFLO (ardeparin sodium)
FDA Docket No.: 97E-0367